REDUCING THREATS TO OUR NATION'S AGRICULTURE: AUTHORIZING A NATIONAL BIO AND AGRO-DEFENSE FACILITY

HEARING

BEFORE THE

SUBCOMMITTEE ON EMERGING THREATS, CYBERSECURITY, AND SCIENCE AND TECHNOLOGY

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REDUCING THREATS TO OUR NATION'S AGRICULTURE: AUTHORIZING A NATIONAL BIO AND AGRO-DEFENSE FACILITY

Wednesday, May 23, 2007

U.S. HOUSE OF REPRESENTATIVES,
COMMITTEE ON HOMELAND SECURITY,
SUBCOMMITTEE ON EMERGING THREATS, CYBERSECURITY,
AND SCIENCE, AND TECHNOLOGY,
Washington, DC.

The subcommittee met, pursuant to call, at 1:58 p.m., in Room 311, Cannon House Office Building, Hon. James Langevin [chairman of the subcommittee] presiding.

Present: Representatives Langevin, Thompson, Christensen, Etheridge, and McCaul.

Mr. LANGEVIN. [Presiding.] The subcommittee will come to order. The subcommittee is meeting today to receive testimony on the need for a national bio-and agro-defense facility.

Good afternoon, and welcome to the Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology hearing on the need to reduce threats to our nation's agriculture sector.

Today, the subcommittee will receive testimony regarding the National Bio-and Agro-Defense Facility, known as NBAF. We are all well aware that biological threats, both man-made and naturally occurring, present a real danger to the security of the United States. In previous hearings, we have heard from experts on how best to protect against a variety of biological threats and how to strengthen programs like BioShield, to effectively procure countermeasures. Today, we will focus our attention on protecting against zoonotic diseases, which affect both animals and humans, and can be devastating to our agricultural sector.

The agriculture industry is a critical component of our economy and is responsible for much of our nation's food supply. We must therefore do everything possible to ensure its safety and security, and this includes strengthening our defenses against zoonotic diseases. Investing in research and development will yield new and innovative technologies and allow us to effectively combat these diseases. These advances will aid in our understanding of disease transmission and development of countermeasures to mitigate disease outbreaks.

For over 50 years, the Plum Island Animal Disease Center has served this nation as a key research facility for foreign animal diseases. That facility is now over a half-century old, and both of the departments represented here today agree that an upgraded facil-

ity is necessary. For years, Plum Island was one of many animal disease research centers run by the U.S. Department of Agriculture, and it fulfilled a unique function partly due to its placement on an island off the U.S. mainland.

Current law, which dates back to 1948, requires that live foot-and-mouth disease virus must be studied on an island to protect against an outbreak on the U.S. mainland. This law has served us well through the years, but experts, including our witnesses today, believe that current containment technology is safe enough for this virus to be studied on the U.S. mainland within the confines of a proper facility.

Today, we will hear from officials both from DHS and USDA on a proposal to change current law to allow for a National Bio-and Agro-Defense Facility. The NBAF will be a new and secure facility—located on the mainland—capable of housing a broad range of zoonotic diseases. The NBAF will significantly enhance our knowledge of these agents and will advance our capability to produce effective countermeasures.

We have certainly seen the devastation that can be caused by the outbreak of zoonotic diseases, such as foot-and-mouth disease. The outbreak of foot-and-mouth disease in the United Kingdom in 2001 caused 2,000 cases of the disease in farms throughout the British countryside. To stop the spread of the disease, seven million sheep and cattle were killed, and all together the crisis is estimated to have cost Britain eight billion pounds, the equivalent of $15 billion.

This crisis emphasizes the ongoing need for foot-and-mouth disease research to provide vaccines and other countermeasures to protect the cattle, dairy, pork and sheep industries. It also highlights the importance of having a state-of-the-art facility with Bio-Safety Level 3 and 4 capabilities to ensure that the diseases studied there will not present a threat to the food and agriculture sectors of our economy. I believe that the proposed facility can meet these challenges, and I laud both the Department of Homeland Security and the Department of Agriculture for their forward thinking on this issue.

As you know, the committee is currently working on a bill introduced by Ranking Member McCaul to authorize such a facility. I am a proud cosponsor of that legislation and I commend the ranking member for his leadership on this issue. The committee has been talking to our colleagues on the Committee on Agriculture, members of the administration represented by our witnesses here today, and several professional organizations regarding the bill language. We appreciate the feedback of our experts, such as our witnesses here today, and we plan to have the bill ready for a markup in a few weeks.

I again want to thank the witnesses for being here today, and I look forward to your testimony.

The chair now recognizes the ranking member of the subcommittee, the gentleman from Texas, Mr. McCaul, for an opening statement.

PREPARED OPENING STATEMENT OF THE HONORABLE JAMES LANGEVIN, CHAIRMAN, SUBCOMMITTEE ON EMERGING THREATS, CYBERSECURITY, AND SCIENCE AND TECHNOLOGY

- Good Afternoon.

• Today the subcommittee will receive testimony regarding the National Bio- and Agro-Defense Facility (NBAF).
• As this subcommittee has become well aware due to numerous hearings on the topic, biological threats, both manmade and naturally occurring, present a real danger to the security of the United States.
• A critical piece of our defenses against such threats are scientific and technological advances in our understanding of disease transmission, and development of countermeasures to mitigate disease outbreaks.
• The Agriculture industry is one of the backbones of our economy.
• In addition to economic impacts, zoonotic diseases, those diseases that affect both animals and humans, are a threat to public safety.
• For over 50 years, the Plum Island Animal Disease Center has served this nation as a key research facility for foreign animal diseases.
• That facility is now over 50 years old and both of the Departments represented here today agree that an upgraded facility is necessary.
• Plum Island was for years one of many animal disease research centers run by the U.S. Department of Agriculture (USDA).
• It did fulfill a unique function, however, because of it's placement on an island off the U.S. mainland.
• Current law, which dates back to 1948, requires that live foot and mouth disease virus be studied on an island to protect against an outbreak on the U.S. mainland.
• This law has served us well through the years, but experts, including our witnesses today, believe that current containment technology is safe enough for this virus to be studied on the U.S. mainland within the confines of a proper facility.
• No one takes this proposed change in policy lightly.
• The outbreak of foot and mouth disease in the United Kingdom in 2001 caused 2,000 cases of the disease in farms in most of the British countryside.
• To stop the spread of the disease, seven million sheep and cattle were killed.
• The crisis is estimated to have cost Britain λ8 billion pounds or $15 billion.
• This crisis emphasizes the ongoing need for foot and mouth disease research to provide vaccines and other countermeasures to protect the cattle, dairy, pork, and sheep industries.
• It also highlights the importance of having a state of the art facility with Bio-Safety Level 3 and 4 capabilities to ensure that the diseases studied there will not present a threat to the food and agriculture sectors of our economy.
• I believe that the proposed facility can meet these challenges, and I commend both the Department of Homeland Security and the Department of Agriculture for their forward thinking on this issue.
• As you know, the committee is currently working on a bill introduced by Ranking Member McCaul to authorize such a facility.
• I am a proud cosponsor of that legislation.
• The committee has been talking to our colleagues in the Committee on Agriculture, members of the administration represented by our witnesses today, and several professional organizations regarding the bill language.
• We appreciate the feedback of our experts and we plan to have the bill ready for a markup in a few weeks.
• The information that we receive today will continue to inform that process.
• I thank the witnesses for being here today and I look forward to you testimony.

Mr. MCCAUL. I thank the chairman for holding this hearing today.

I must say, while I was disappointed that my provision authorizing the National Bio-and Agro-Defense Facility was stripped from the DHS authorization bill, I do appreciate and applaud your efforts and Chairman Thompson's to move H.R. 1717 as a stand alone bill, and look forward to marking it up in the coming weeks.

I realize that the problem we ran into with this provision being included in the authorization, along with many others, were due to overlapping interests with other committees. Even so, I don't think there is any disagreement that NBAF is a crucial component to our nation's strategy to defend against agro-terrorism, and that NBAF will address unmet needs.

As I have stated before, there is currently no BSL–4 capability for research on zoonotic diseases, and we shouldn't let turf battles prevent the department from addressing these issues and having the tools that it needs to protect this country. My staff is currently in the process of fine-tuning H.R. 1717, along with your staff, to make it clear that NBAF will be a coordinated interagency effort with an over-arching homeland security mission. They are reaching out to the relevant stakeholders in the agricultural community such as the National Cattlemen's Beef Association and the Animal Agriculture Coalition to ensure that H.R. 1717 addresses and meets the needs of the agricultural community.

Clearly, the time is right now to foster collaboration between veterinary medicine, human medicine, public health and the environmental health sciences. DHS is positioned to do this with NBAF. Through the years, DHS's fundamental research and DHS's targeted advance development of this facility will help protect the veterinary, food and agriculture industries of the United States.

I hope we—"we" being the congressional committees with the oversight of agro-terrorism activities—can lead by example and present a unified effort to move H.R. 1717 forward.

I want to thank our witnesses for appearing here today. I hope your due diligence and the NBAF site selection process continues unabated as we look to this future capability. I look forward to hearing from each of you about how you are working together on foreign animal and zoonotic disease research and how that relationship will transition when NBAF stands up.

I yield back my time.

PREPARED OPENING STATEMENT OF THE HONORABLE MICHAEL T. MCCAUL, RANKING MEMBER, SUBCOMMITTEE ON EMERGING THREATS, CYBERSECURITY, AND SCIENCE AND TECHNOLOGY

- Thank you Chairman Langevin for holding this hearing today. While I was deeply disappointed that my previously accepted provision authorizing the National Bio and Agro-Defense Facility was stripped from the DHS Authorization bill at the last minute, I appreciate your efforts to move HR 1717 as a stand alone bill and look forward to marking it up in the coming weeks.
- I recognize that part of the problem we ran into on this provision, and with many others that were removed from the authorization bill, were due to overlapping interests with other Committees.
- With the NBAF in particular, there is no way around the interests of the homeland security and the agriculture communities coinciding. The NBAF will be a facility that supports the mission of not just DHS, but USDA as well and, in some cases, the Department of Health and Human Services.
- The integrated nature of NBAF is the heart of the issue, and it's at the heart of what will drive NBAF's success in supplying our Nation with the tools it needs to combat agroterrorism.
- I don't think that there is any disagreement among the agencies or among the agriculture and homeland security communities that NBAF is a crucial component to our Nation's strategy to defend against agroterrorism, and address unmet needs. HSPD 9 identified the need to increase and enhance our laboratory infrastructure for studying foreign animal and zoonotic diseases. NBAF will not only retain the research and diagnostic development and validation now being conducted at the aging Plum Island Animal Disease Center, but it will greatly enhance capabilities.
- There currently is no BSL 4 capability for this type of research. NBAF will provide this unique capability.
- We shouldn't let turf battles and power struggles prevent the Department from having the mechanisms it needs to establish this facility and open its doors to collaborative research among the agencies and the agriculture community at large.

• My staff is in the process of fine tuning HR 1717 to make it more clear that while NBAF's walls will be owned by DHS, inside you'll find a coordinated, interagency effort with an overarching homeland security mission. They are reaching out to the relevant stakeholders in the agricultural community, such as the National Cattlemen's Beef Association and the Animal Agriculture Coalition, to ensure that H.R. 1717 addresses and meets the needs of the agriculture community.
• The NBAF will exemplify the concept of "one medicine," where research will be conducted at the interface of animal, human, public and ecosystem health.
• Think of the health threats that have grabbed headlines over the past decade—bird flu, mad cow disease, SARS, West Nile virus, monkey pox, antimicrobial resistance. These have heightened awareness of the role animal populations play in transmitting health risks to humans the world over.
• 75% of the emerging infectious disease threats affecting people in the past decade are zoonotic, meaning they also affect or arise from animals. Approximately 80 % of the top biological threat agents are zoonotic diseases.
• But when we speak of threats to human health, we must think beyond disease transmission from animals to humans. Some animal diseases, even if they don't affect human health, have adverse consequences on the well being of the human population.
• For example, while Foot and Mouth Disease, a foreign animal disease, only affects cows, swine, sheep, goats, and other hooved animals, it also has secondary impacts on our domestic and global economy. An outbreak of FMD could result in billions of dollars of economic impact. Tens of thousands of people would be affected with regard to jobs, income, and an altered way of life.
• The Department of Homeland Security has brought a sense of urgency to research efforts to produce countermeasures for diseases of high consequence to humans and animals, the economy, and the environment. These include the foreign animal and zoonotic diseases I have mentioned.
• Clearly the time is right to embrace the one medicine concept and foster collaboration between veterinary medicine, human medicine, public health, and the environmental health sciences.
• DHS is positioned to do this with the NBAF. Through the USDA's fundamental and innovative efforts and DHS' targeted advanced development, this facility will serve the future needs of and help protect the veterinary, food, and agriculture industries of the U.S.
• I hope we—"we" being the congressional committees with oversight of agroterrorism activities—can lead by example, present a unified effort to move HR 1717 forward and instill in the agencies which we oversee the same unity of effort which encompasses the principle of the "one medicine" concept.
• I want to thank our witnesses for appearing before us today. I hope your due diligence in the NBAF site selection process continues unabated as we look to this future capability. I look forward to hearing from each of you about how you are currently working together on foreign animal and zoonotic disease research and diagnostics and how that relationship will transition when NBAF stands up.

Mr. LANGEVIN. I thank the ranking member.

The chair now recognizes the chairman of the full committee, the gentleman from Mississippi, Mr. Thompson, for an opening statement.

Mr. THOMPSON. Thank you very much, Mr. Chairman. I want to thank you for holding this hearing on what is clearly a vital issue facing our nation.

Many of us remember the stir caused when former Secretary of Health and Human Services Tommy Thompson announced his resignation, warning that the U.S. food supply could be a lethal target for terrorists and we are at significant risk of a flu pandemic.

Homeland Security Presidential Directive 9, issued in 2004, identified the need for safe, secure and state-of-the-art biosafety laboratories that research and develop diagnostic capabilities for foreign animal and zoonotic diseases—those that infect both animals and humans. We understand that Plum Island Animal Disease Center

in New York is currently performing much of this research and is nearing the end of its life cycle.

The threat of foreign animal diseases, especially zoonotic diseases, to the public health and the agriculture industries has been a reality for many years. The Committee on Homeland Security recognizes the need for increased vigilance in fighting and protecting against the spread of current and future infectious diseases that threaten public health and agriculture.

We also understand that the current research lab at Plum Island was designed primarily to study the accidental introduction of foreign disease agents, and not the additional research needed to prepare for an intentional bioterrorism attack.

I am pleased this committee is moving forward with efforts to address the issue of the aging research facility, act on the guidance offered through HSPD–9, and assess the current working relationships between the DHS and USDA.

I look forward to hearing from the witnesses today regarding the need for an NBAF facility and meeting the requirements of Homeland Security Presidential Directive 9. I thank the chairman for his time and I yield back the balance.

Mr. LANGEVIN. I thank the chairman.

The other members of the subcommittee are reminded that under the committee rules, opening statements may be submitted for the record.

I would like to now welcome our witnesses. Our first witness, Dr. John Vitko, is currently the division head of the Chemical and Biological Division of the Science and Technology Directorate in the Department of Homeland Security. In that role, he has the overall responsibility for all DHS S&T to deter, detect and mitigate a biological or chemical attack on the people, infrastructure, or agriculture of this nation.

Prior to that, John was director of exploratory systems at Sandia National Laboratory in Livermore, California, where he has been since receiving his Ph.D. in physics from Cornell University in 1975.

Our second witness is Dr. Edward Knipling, the administrator of the Agricultural Research Service. He began his career with the Agricultural Research Service in 1968 as a research plant physiologist in Gainesville, Florida. He has held many positions in ARS, including area director, associate deputy administrator, director, and deputy administrator of the Beltsville Agricultural Research Center. Dr. Knipling served as acting administrator and associate administrator of ARS in December 1997. Dr. Knipling was appointed administrator of ARS in July, 2004.

He earned his BS degree in 1961 in forestry from Virginia Tech University. He received his MA degree in 1963 and Ph.D. in 1966 in plant physiology from Duke University.

Dr. Knipling will be giving testimony for both himself and our other witness, Mr. Kevin Shea. Kevin Shea was appointed associate administrator of the Animal and Plant Health Inspection Service, APHIS, on September 9, 2004. In his position, he is responsible for ensuring the smooth day-to-day functions of APHIS. Mr. Shea spent 4 years as head of APHIS's policy and program development staff. Before becoming director of PPD, Mr. Shea served as director

of APHIS's budget and accounting division for 8 years, and similar positions within APHIS where he has been almost continuously since 1978, taking a 1 year hiatus to practice litigation.

Mr. Shea graduated from the University of Maryland at College Park and earned his juris doctorate from the University of Baltimore School of Law.

Gentlemen, welcome here today. Without objection, the witnesses' full statements will be inserted into the record. I will now ask each witness to summarize their statement in 5 minutes, beginning with Dr. Vitko.

Welcome.

STATEMENT OF JOHN VITKO, Jr. HEAD, CHEMICAL AND BIOLOGICAL DIVISION, SCIENCE AND TECHNOLOGY DIRECTORATE, DEPARTMENT OF HOMELAND SECURITY

Mr. VITKO. Thank you. Good afternoon, Chairman Langevin, Ranking Member McCaul, full committee Chairman Thompson, and distinguished members of the subcommittee.

My name is Dr. John Vitko. I am the head of the Chemical and Biological Division of the Science and Technology Directorate of the Department of Homeland Security. In that role, I have overall responsibility for all DHS science and technology programs related to bio-and agro-defense, and work very closely with our colleagues in the United States Department of Agriculture.

In that role, I am pleased to appear before you today to speak to the need for the National Bio-and Agro-Defense Facility, NBAF, and to give you some idea of the important work that will be done there. NBAF is vitally needed to meet the foreign animal and zoonotic disease challenges for today and for the next 50 years.

There are three key drivers underlying that need. One, foreign animal and zoonotic diseases can have a major impact on our economy, food supply and public health. The threats to the nation's agriculture and public health have changed dramatically since the time of the establishment of Plum Island. These changes include the globalization of travel and trade, the broadened size and scope of the U.S. livestock and agricultural industry, newly emerging diseases, and now the threat of agro-terrorism.

Second, the Plum Island Animal Disease Center, which has been the first line of the nation's defense against foreign animal diseases for the past 50 years, is unable to fully address this growing threat of agro-terrorism. Its limited laboratory space, especially that for testing large animals, is limiting the pace of the development of vaccines for foot-and-mouth disease, and also the ability to expand programs addressing the numerous other high-priority foreign animal diseases of concern.

Third, the nation lacks a facility for addressing high-consequence zoonotic diseases that infect both large animals and humans. The impact of disease agents such as Rift Valley fever, Nipah, and Hendra viruses underscore the growing threat posed by emerging zoonotic diseases.

As already referenced by Chairman Thompson, the president, in his defense of United States agriculture and food, called for planning for state-of-the-art agricultural biocontainment laboratories that research and develop diagnostic capabilities for foreign animal

and zoonotic diseases. That same HSPD called for expanding the development of current and new countermeasures against both intentional and natural introductions of those diseases.

NBAF is being designed to fulfill both those requirements and to support our needs and our partners in the United States Department of Agriculture. NBAF will provide state-of-the-art biocontainment laboratories for the development, testing, and evaluation of diagnostics and countermeasures of foreign animal and zoonotic diseases.

It will integrate those aspects of animal and public health research that are key to fulfilling that mission. It will help attract, train and retain future generations of researchers, technicians, diagnosticians, veterinary and medical personnel. By so doing, it will continue to meet evolving needs in defending against agro-terrorism over the next 5 decades.

NBAF is being designed to concurrently develop multiple priority vaccine candidates, and to enable the broad range of activities needed to support that development. Those activities include basic research on how organisms infect animals and how that infection is transmitted from animal to animal; identification of lead candidates for new vaccines and antivirals; novel delivery systems, think of that as ways of administering medicine to speed response actions; pilot lot production and testing of vaccines; clinical testing to support licensure and for inclusion in national veterinary stockpiles; the development of diagnostics to rapidly identify, characterize and control outbreaks; and the training of veterinarians to establish a rapid response capability throughout the United States.

NBAF will be operated in partnership with and support of our colleagues in the Department of Agriculture, in much the same manner that we are currently operating the Plum Island Animal Disease Center.

In summary, NBAF is vital to meeting the agro-defense needs of the nation for the next 50 years, just as PIADC has been vital to meeting those needs for the past 50 years. Therefore, we at DHS are committed to making NBAF a reality to support our partners in the Agricultural Research Service, and in the Animal and Plant Health Inspection Service.

Thank you. This concludes my testimony.

[The statement of Mr. Vitko follows:]

PREPARED STATEMENT OF DR. JOHN VITKO, JR.

INTRODUCTION

Good afternoon, Chairman Langevin, Ranking Member McCaul, and distinguished members of the Subcommittee. I am pleased to appear before you today to discuss the Nation's critical need for the Department of Homeland Security's National Bio and Agro Defense Facility.

There is a need for a secure, state-of-the-art agriculture biocontainment facility that researches and diagnoses foreign animal and zoonotic diseases. Currently, there is only a limited research laboratory capacity in the Nation for large animal BioSafety Level-3 (BSL–3Ag) studies, and there is no BSL–4 research space for the study of threat agents that infect both large animals and humans. If the United States is to have the proper capability to rapidly identify and control outbreaks of high-threat foreign animal and zoonotic disease agents, whether natural or intentional, it must begin investing in additional biocontainment capacity and capability.

Numerous infectious animal diseases are present throughout the world that threaten the nation's public health, agriculture and economy. For example, recall the foot-and-mouth disease outbreak in the U.K. in 2001 and the catastrophic losses

that this outbreak caused that nation, and from which it is still recovering now six years later. The economic loss was well into the billions, affecting agricultural industries but having a wider impact on other industries including tourism. The impact would be far greater in the U.S, with its much larger livestock population, larger herds, and extensive shipment across the country.

As evidenced by recent examples, including West Nile Fever and Avian Influenza, existing and emerging foreign animal and zoonotic diseases pose an immediate threat not only to our agricultural industry but also to our public health.

Realizing this threat, the President issued Homeland Security Presidential Directive 9: *Defense of the U.S. Agriculture and Food.* HSPD–9 requires the Secretaries of Agriculture and Homeland Security , Health and Human Services, and the Administrator of the Environmental Protection Agency to "develop a plan to provide safe, secure and state-of-the-art agricultural biocontainment laboratories that research and develop diagnostic capabilities for foreign animal and zoonotic diseases" and further states that "The Secretaries of Homeland Security, Agriculture. . .will accelerate and expand development of current and new countermeasures against intentional introduction or natural occurrence of catastrophic animal, plant and zoonotic diseases." As will be elaborated in the following sections, NBAF fulfills a critical role in meeting both these requirements and ensuring that the nation's public health, food and agriculture are protected for the next 50 years.

In pursuing NBAF, DHS will work closely with its partners in the United States Department of Agriculture under the same terms and spirit as it currently does at the Plum Island Animal Disease Center.

The Need for NBAF

For more than 50 years, the Plum Island Animal Disease Center (PIADC) has served as the nation's first defense against foreign animal diseases. However, the threats to the Nation's agriculture and public health have changed dramatically since the time of PIADC's establishment. These changes include the globalization of travel and trade, the broadened size and scope of U.S. livestock and agricultural industry, and now the threat of agro-terrorism. PIADC's research and diagnostic activities stem from its mission to protect U.S. animal industries and exports from deliberate or accidental introduction of foreign animal diseases. PIADC has been a leader in researching foreign animal diseases, developing diagnostics and vaccines to prevent and contain them, and training foreign animal disease diagnosticians to detect them. The Homeland Security Act of 2002 transferred the operations of PIADC to DHS. Since that time, the DHS Science & Technology Directorate has been working jointly with the United States Department of Agriculture's Agricultural Research Service (ARS) and Animal and Plant Health Inspection Service (APHIS) to meet the island's shared mission objectives.

However, despite significant investments in the facility's infrastructure, Plum Island Animal Disease Center is unable to fully meet the research and diagnostic capabilities required to address the threat of agro-terrorism. The available laboratory space at PIADC, especially the large animal holding laboratory space, is limiting the pace at which we can develop improved veterinary countermeasures. The joint USDA–DHS team has made significant progress in developing next-generation vaccines for foot-and-mouth disease. The path forward for such state-of-the art vaccines includes taking these discoveries through developmental and testing phases for licensure necessary for inclusion in the National Veterinary Stockpile and for eventual use by first responders. However, the limited animal testing space at PIADC is limiting the number of vaccine trials that can be conducted and drastically extending the time frame to complete these studies. Additionally, because of capacity and biocontainment constraints, PIADC concentrates on research and diagnostic activities for only a subset of the highest-consequence foreign animal diseases and cannot facilitate expanded research into other high priority foreign animal disease and emerging threats of concern.

Additionally, BSL–4 work cannot be done at PIADC. Thus, the nation lacks a facility to adequately address high-consequence zoonotic diseases that infect both large animals and humans. The impact of disease agents, such as Rift Valley Fever, Nipah, and Hendra, underscore the growing threat posed by emerging zoonotic diseases and the need to establish better facilities to study them.

To address these limitations, the planned NBAF will provide the infrastructure necessary to research and develop diagnostics for, and countermeasures to, high-consequence biological threats involving foreign animal and zoonotic diseases by:

- Providing state-of-the art biocontainment laboratories for development, test and evaluation of countermeasures for foreign animal and zoonotic diseases to support their inclusion in the National Veterinary Stockpile;

- Integrating those aspects of animal and public health research that are key to fulfilling that mission;
- Continuing to meet evolving needs in defending against agro-terrorism threats over the next five decades.

Plum Island Animal Disease Center's capability is a critical national asset and essential to protecting the U.S. agriculture economy and food supply. No other facility now exists in this country to perform this research. However, due to its age, location and outdated design, PIADC does not meet all of the nation's current needs. The planned NBAF will enable us to fully meet the challenges of intentional or unintentional introduction of a foreign animal disease that could threaten public health and the food supply over the next 50 years.

The Scope of NBAF

NBAF is being designed to provide the Nation with the "safe, secure, and state-of-the-art agriculture biocontainment laboratories" (HSPD–9) needed to develop countermeasures to current, emerging and future foreign animal and zoonotic diseases. The facility design will enable concurrent development of multiple priority vaccine candidates. It will also meet the shared interagency mission objectives of a successful agro-defense strategy, including:

- basic research on how an organism infects an animal and how the disease is transmitted from animal to animal;
- identification of 'lead candidates' for new vaccines and antivirals and novel delivery systems to better facilitate response actions;
- pilot lot production and proof-of-concept testing of those lead candidates;
- the development of molecular diagnostics to characterize the efficacy of the new countermeasures;
- clinical testing and evaluation of the countermeasures to support licensure by the USDA Center for Veterinary Biologics and inclusion in the National Veterinary Stockpile;
- maintain a vaccine bank that contains a secure inventory of antigens that would be used to formulate a vaccine in the event of an outbreak;
- develop and test diagnostics to rapidly identify, characterize, and control outbreaks;
- train veterinarians, giving them first hand experience in recognizing and diagnosing high consequence foreign animal diseases and thereby establishing a clinical capability for rapid response throughout the U.S.

DHS, in close coordination with USDA, is actively engaged in the definition of these program areas and the conceptual design of facility aspects to best support them. Additionally, USDA personnel are active participants in the NBAF site selection process. The conceptual design is independent of the site selected and will ensure that the NBAF's research requirements will be met. Such a state-of-the-art facility will synergize with existing veterinary, medical and public health, and agriculture programs and will help attract, train and retain future generations of researchers, technicians, diagnosticians, veterinary and medical personnel.

DHS has begun taking the steps to make this vision a reality. In January of 2006 DHS issued a notice of request for Expressions of Interest (EOI) for potential sites for the NBAF in the Federal Register and received 29 submissions from consortia in 21 states. An interagency review committee (DHS, USDA, HHS and DoD) evaluated the site proposals using four major sets of criteria which had been published in the EOI notice of request:

- Site proximity to Research Capabilities that can be linked to NBAF mission requirements
- Site proximity to a skilled Workforce to support NBAF mission requirements
- Acquisition/Construction/Operations; and
- Community Acceptance

Based on this initial evaluation, 12 consortia in 11 states were asked to submit additional information on 17 sites. That information is currently under review. In addition, the review team and the DHS Under Secretary for Science and Technology are visiting each of the sites for further evaluation. Following the site visits, a small number of sites will be selected for inclusion in the Environmental Impact Statement (EIS). This selection will be completed by June 2007. The final site selection will be determined following completion of the EIS.

Key milestones and anticipated dates in this process are summarized below:

Additional information due	February, 2007

Conduct reviews	March, 2007
Site visits	April—May, 2007
Issue Notice of Intent (NOI) announcing sites selected for evaluation in the EIS	June, 2007
Begin EIS	July, 2007
Complete EIS; announce site selection	October, 2008
Begin detailed design	November, 2008
Begin construction	2010
Facility operational	2013—2014

Conclusion

In summary, the planned NBAF will play a crucial role in protecting the Nation against current and future foreign animal and zoonotic diseases, whether naturally or intentionally introduced. The list of such high priority diseases is already long and growing. Plum Island has been doing an excellent job in the defense against foreign animal disease threats—but the age of its facilities and its limited capacity is pacing the development of needed countermeasures. Further, there are no facilities in the Nation to fully address those zoonotic diseases that affect both large animals and humans and attract the scientists, technicians, researchers, veterinarians and medical personnel needed to defend against current and future threats for the next 30—50 years. Therefore, DHS is committed to making the planned NBAF, as the next generation capability to support our partners in ARS and APHIS, a reality.

Mr. LANGEVIN. Thank you, Dr. Vitko. Thank you for your testimony.

I would like to now recognize Dr. Knipling to summarize your statement for 5 minutes.

STATEMENT OF EDWARD KNIPLING, ADMINISTRATOR, AGRICULTURAL RESEARCH SERVICE, U.S. DEPARTMENT OF AGRICULTURE

Mr. KNIPLING. Mr. Chairman, Chairman Thompson, Ranking Member McCaul, and other members of the subcommittee, I am Dr. Edward Knipling, administrator of the USDA Agricultural Research Service. Thank you for the opportunity to appear before the subcommittee today to present the department's views on the establishment of NBAF.

I will provide brief oral comments to summarize the principal points in my written testimony, and to reinforce and supplement those just provided by Dr. Vitko of DHS.

First, let me acknowledge once again that accompanying me today from USDA is Mr. Kevin Shea, associate administrator of the Animal and Plant Health Inspection Services, APHIS. APHIS is the regulatory and operations arm of the department responsible for protecting and promoting U.S. agriculture, including diagnostics, training, and development of products related to the prevention and control of animal diseases.

The ARS is the intramural science research arm of the USDA. We make basic science discoveries and develop new technologies needed and used by APHIS, DHS, other agencies, and in fact the entire food and agricultural system to protect and advance U.S. agriculture.

My comments today will address two main points: one, the need for and the merits of NBAF relative to the limited capabilities of the existing facilities at the Plum Island Animal Disease Center; and two, to describe the agreements and mechanisms USDA and DHS already have in place to ensure cooperation, complementarity,

and coordination of our respective programs and operations at Plum Island and elsewhere, and to be continued in the new NBAF.

Mr. Chairman, the need to establish NBAF is basically two-fold. First, it is needed to replace the aging facility at Plum Island; and second, it is needed to provide additional space and capability, including large animal biosafety level 4 laboratories to study and develop controls and countermeasures for high-consequence foreign animal pathogens that threaten the U.S. livestock industry, some of which could also be transmitted to humans, thus threatening public health as well.

It is already well pointed out that the current facilities at Plum Island are outdated, and otherwise inadequate. NBAF will fulfill the new needs for the nation.

Regarding USDA and DHS cooperation and coordination, the Homeland Security Act of 2002 required the secretary of homeland security and the secretary of agriculture to enter into an agreement to ensure that USDA is able to carry out research, diagnostics and other USDA activities at Plum Island. Accordingly, the two agencies of USDA, ARS and APHIS, and the Science and Technology Directorate of DHS, entered into an interagency agreement dated June 1, 2003, which together with successor annual agreements, set forth the terms for the management, administration and operations at Plum Island.

According to this agreement, a board of directors is composed of the directors of the DHS Science and Technology Directorate, and the administrators of ARS and APHIS. This includes Dr. Vitko, myself, and the APHIS administrator, Dr. Ron DeHaven, represented here today by Mr. Shea.

Additionally, a senior leadership group composed of the on-site leaders for each agency at Plum Island implement programs and policies, coordinate at the local level, and report to the board of directors.

A copy of the interagency agreement document executed in 2006 for the current 2007 fiscal year has previously been provided to the subcommittee for the record, along with my written testimony. This document also spells out in general terms the division of program responsibilities among the three agencies with respect to foreign animal diseases.

Very simply, the role of ARS is basic and applied research. APHIS's responsibilities include disease diagnostics, training and the maintenance of a vaccine stockpile. DHS's responsibilities are to build upon and extend USDA's work to develop and evaluate advanced animal disease countermeasure products, in concert with the private sector. Foot-and-mouth disease is the primary focus of the animal pathogen work at Plum Island, but some other diseases are also addressed.

The complementary and coordinated responsibilities, program strategies and plans of work of the three agencies are outlined in much greater detail in the two documents also provided to the subcommittee for the record. These documents are entitled, one, "A Comprehensive Strategy to Combat Agro-Terrorism," issued by DHS in 2004; and the second, "A Joint DHS and USDA Strategy for Foreign Animal Disease Research and Diagnostic Programs," also issued in 2004.

Mr. Chairman, this concludes my remarks. Both Mr. Shea and I would be pleased to answer any questions that you have of USDA.

Thank you.

[The statement of Mr. Knipling follows:]

PREPARED STATEMENT OF DR. EDWARD KNIPLING

Mr. Chairman, Ranking Member McCaul, and Members of the Subcommittee, I am Dr. Edward Knipling, Administrator of the Agricultural Research Service (ARS). Accompanying me is Mr. Kevin Shea, Associate Administrator of the Animal and Plant Health Inspection Service (APHIS). ARS is the primary intramural science research agency of USDA, operating a network of over 100 research laboratories across the nation on all aspects of agricultural science. APHIS is responsible for protecting and promoting U.S. agricultural health, administering the Animal Welfare Act, and carrying out wildlife damage management activities.

Thank you for the opportunity to appear before the Subcommittee today to present the Department's views on the establishment of the National Bio and Agro-Defense Facility (NBAF).

Mr. Chairman, the need to establish this facility is basically two fold: First, it is needed to replace the aging foreign animal disease research, diagnostic and training facility at Plum Island; and, second, it is needed to provide additional space and capability for animal borne diseases that can be transmitted to humans. Homeland Security Presidential Directive No. 9 (HSPD–9) identifies the need for "safe, secure, and state-of-the-art agricultural biocontainment facilities to research and develop diagnostic capabilities for foreign animal and zoonotic diseases." Current limitations at existing facilities result in a backlog of needed space for important experiments, diagnostics, and training efforts.

Despite the planned replacement of the Plum Island Animal Disease Center (PIADC) with NBAF, the PIADC must continue to operate during NBAF construction and beyond to allow adequate transition to the new facility and eventual facility decommissioning at Plum Island. It is estimated that PIADC facilities must operate for about the next 7—10 years. The highest priority for facility upgrade includes the construction of additional animal holding (experiment) facilities (10,000 ft2) and expansion of the necropsy room capacity. The additional capacity is needed to address the coordinated USDA–DHS vaccine development program over the next 7—10 years.

The upgrade and expansion of the necropsy facility will also improve our current educational facility for the foreign animal disease (FAD) training schools carried out by APHIS at PIADC. APHIS conducts these training schools on Plum Island to ensure that our Nation's corps of foreign animal disease diagnosticians—those specially trained veterinarians immediately dispatched by APHIS to investigate and, if necessary, respond to possible introductions of exotic animal diseases into the United States—have the latest scientific and technical information and skills necessary to carry out their work. APHIS also conducts its confirmatory testing for extremely contagious foreign animal diseases, such as foot-and-mouth disease (FMD), at the PIADC. In addition, the Agency houses the North American Foot-and-Mouth Disease vaccine bank on PIADC. The bank ensures that if FMD were to be found in North America and vaccination was to be used as a tool in the ensuing control and eradication program, adequate supply of vaccine would be quickly available to animal health officials.

Under Section 310(a) of the Homeland Security Act of 2002, the Secretary of Agriculture transferred PIADC to the Secretary of Homeland Security, including the assets and liabilities of PIADC. Section 310(b) of the Act required the Secretary of Homeland Security and the Secretary of Agriculture to enter into an agreement upon such transfer to ensure that USDA is able to carry out research, diagnostic, and other activities of USDA at PIADC. USDA–ARS, USDA–APHIS and DHS–S&T entered into an Interagency Agreement dated June 1, 2003, ("the FY03 Agreement) which together with successor agreements sets forth the Parties' agreements regarding the management, administration, and operations of PIADC, and the Parties' respective rights and responsibilities for research, diagnostic, and development activities at PIADC. According to this agreement, a Board of Directors (BOD) is composed of the Directors or Administrators of APHIS, ARS and DHS–S&T Directorate. A Senior Leadership Group (SLG), composed of the senior administrators of each agency at PIADC, executes the FY03 Agreement, implements policies, coordinates at the local level and reports to the BOD.

DHS's work currently focuses primarily on FMD; whereas ARS, in addition to FMD, also addresses other diseases, specifically classical swine fever and vesicular stomatitis. A FMD countermeasure roadmap was prepared in 2004 to coordinate DHS and ARS activities. According to this document, ARS would maintain responsibility for basic research, and DHS would focus on product development. A high priority disease diagnostic roadmap was prepared in 2006 to coordinate DHS, ARS, and APHIS activities in this area.

Mr. Chairman this concludes my remarks. We would be happy to answer any questions at this time.

Mr. LANGEVIN. Thank you, Dr. Knipling.

I want to thank all the witnesses for their testimony today.

I will remind each member that he or she will have 5 minutes to question the panel. I now recognize myself for questions.

To the panel, as I mentioned in my opening remarks, and as Dr. Vitko also stated, an outbreak of foot-and-mouth disease, otherwise known as FMD, could be extremely damaging to the agricultural sector and our overall economy in general. One of the major concerns regarding NBAF is, of course, the studying of live foot-and-mouth disease virus on the U.S. mainland, which has historically been studied on Plum Island.

You all seem to be in agreement that FMD can be safely studied on the mainland. Can you please explain in more detail for the committee what protective measures would be in place and what improvements in technology have occurred to make such research safe? Is there any extra concern with respect to foot-and-mouth disease that, for example, wouldn't be present with other pathogens such as ebola or hantavirus that would need to have particular concern as to why it should be studied off the mainland.

This has caused concern among some in Congress and I am hoping that you can shed a little more light on this so that we can all feel comfortable that this is the right decision.

Mr. VITKO. I would be happy to answer that first. Ed and Kevin may choose to add to that.

First of all, let me say that the handling of FMD poses no additional concerns beyond the agents that you talked about, ebola and Marburg. In fact, those are much more serious because of their human consequences and the lack of countermeasures against those.

The advances in technology that have occurred since the mid–1950s when Plum Island was established is in the sealing, containment, filtration of air systems within any of the biocontainment rooms, and with the development of specialized suits to protect those researchers from exposure to agents that might infect them. That technology has been successfully demonstrated and used for the last couple of decades, in fact, for dealing with the diseases that you mentioned, ebola, Marburg, smallpox, other highly contagious diseases.

Mr. KNIPLING. Mr. Chairman, I would support those comments by Dr. Vitko. I would just reinforce the notion that the physical standards by which facilities are constructed and operated in terms of air pressures, filtration and so forth, prevent the escape of the pathogens to the environment. Foot-and-mouth disease per se is not a zoonotic, that is, not a threat to human health. It is highly contagious to livestock. The off-shore island requirement, originally

that statute goes all the way back to 1884, with just the extra measure of protection to protect the U.S. livestock industry.

We have more than a 50-year record of safety, and along with the new biocontainment facility technology, we can safely conduct this research on the mainland.

Mr. LANGEVIN. Very good. Thank you.

Dr. Knipling, your testimony mentioned that the Animal Research Service, ARS, has the responsibility for basic research, and the FMD the countermeasures roadmap, while DHS focuses on the development of the candidate countermeasures. Dr. Knipling, can you tell me what the focus of your research on FMD is? And Dr. Vitko, can you tell me more about countermeasures development?

I would also like to ask you to characterize the work that is being done now, again, at Plum Island, and compare that work to what you envision occurring at NBAF.

Mr. KNIPLING. Mr. Chairman, I would characterize our complementary and coordinated programs as a linear spectrum of activities progressing from the basic sciences to product development and then actual application for the industry and so forth.

In terms of the basic research of ARS, we are looking at the fundamentals of the virus itself, that there are many different strains of the foot-and-mouth disease virus, for example. Current work stresses genomics, molecular biology, diagnostic techniques. And then the development of the innovative and unique vaccines for protection.

We would hand off, then, these basic discoveries to DHS and other organizations to further develop them.

Mr. LANGEVIN. Thank you.

Mr. VITKO. Picking up on that point, one specific example, as you may know, there is a great deal of interest in developing the next generation of FMD vaccines that allow one to differentiate infected versus vaccinated animals—an important issue for resuming trade should an outbreak occur.

The researchers at ARS have identified several promising candidates for such DIVA vaccines. We have then taken those candidates, produced them in pilot-like quantities that then allow their testing against significant numbers of large animals—cattle in this case—to establish their initial efficacy. Now, we have begun working with a private supplier, an industrial partner, in scaling up that production to manufacturing scale lot sizes, so that we can then go on and do additional tests of the onset of immunity and the duration of immunity that are needed for licensure of this product by the Center for Veterinary Biologics, and for ultimate transition by APHIS into the National Veterinary stockpile.

Mr. LANGEVIN. Thank you, Mr. Vitko.

I now recognize the ranking member of the subcommittee, the gentleman from Texas, Mr. McCaul, for questions.

Mr. MCCAUL. I thank the chairman.

I think to identify the need for this facility, we need to identify what the threat is, both from a natural standpoint, that could impact the food supply, but also man-made to agro-terrorism. I wanted to see if the panel could expand upon what they perceive as the real threat out there, but then also the question of, you know,

Plum Island is a level 3 facility; NBAF would be a level 4. I have visited level 4 facilities.

Can you expand upon the difference there? What type of threat agents could be addressed at NBAF as opposed to the level 3 facility at Plum Island?

Mr. VITKO. As I understand it, you have two parts to your question. One was around the relevant threats and how agro-terrorism is different; and then the second around the agents and the different containment facilities and their requirements.

Mr. MCCAUL. That is correct.

Mr. VITKO. With respect to the first, agro-terrorism actually poses significant different threats than just a natural outbreak, in several major ways. We have been fortunate in this country that in the past the threat of foreign diseases would come primarily across our borders. In that case, we would have some knowledge of the strain that is coming and the introduction point would be a single or small number of introduction points.

Agro-terrorism, with a conscious act or behind it, means that the strain could come from anywhere in the world, whether we have seen it or not, or have it near us or not. And it would be introduced not necessarily just in one location, but could be introduced in multiple locations. And it might not just be one. It might be several different ones.

So this adds a great deal of complexity to the problem of what we need to address, and it shortens the timeframe that we have for addressing anything that we encounter.

Now, with respect to the differences between biosafety level containment 3 and 4, in biosafety level containment 3, we have the kinds of features that both myself and Dr. Knipling talked about before, which was that we have control on the airflow and the air pressures and filtration to control the presence of the agent, and hoods, and that is the primary complement for protecting that.

That BSL–3 is perfectly fine for dealing with agents that don't have significant effects on humans or for which, if they have effects on humans, there are readily available countermeasures. In those cases where that is not the case, so in human diseases, as we mentioned before, Marburg, ebola, smallpox, and in the zoonotic diseases, particularly Nipah and hantaviruses, where there are not readily available countermeasures and which can also infect humans, then there are additional precautions taken for protecting the worker in terms of suiting up restrictions, interlocks for getting in and out, working protocols, and those are applied.

It is important to realize that NBAF will not be all BSL–4. Much of NBAF will be BSL–3 because of the need for studying a large number of foreign animal diseases that are in fact not zoonotic. But where they are zoonotic and at a high level, then they would be studied in a level-4 facility.

Mr. MCCAUL. Thank you.

Any of the other panel members?

Mr. KNIPLING. I would add that another way to characterize the difference between biosafety level 3 and 4 is that the extra measures for level 4 are primarily to protect the human workers—the workers actually working in the facility. In terms of the laboratory physical structure and all of the air handling and access controls,

those would be largely the same. But it is important that we obviously protect the workers in the laboratory itself, and of course prevent these pathogens from escaping into the environment where they could affect not only the livestock industry, but human health as well.

Mr. MCCAUL. In my home state—and I see my time is running out, so I want to get this last question in—of Texas, Texas A&M has a National Center for Foreign Animal and Zoonotic Disease Research. How would you, to the panel, envision NBAF tying into that facility in terms of the research already being conducted there?

Mr. VITKO. Currently, FASDC, the Foreign Animal Zoonotic Disease Center, in fact already works with Plum Island Animal Disease Center on both its vaccine development and its diagnostic development. What FAZDC does and what the consortium there does is develop new vaccine candidates that need to be tested. What NBAF would do is provide that kind of testing, but it would allow us to address a broader range of foreign animal diseases and zoonotic threats.

Mr. MCCAUL. Any of the other witnesses?

Mr. KNIPLING. I would just add that most all of our ARS laboratories across the country—some 100 facilities on all aspects of agricultural science—are mostly co-located with the land-grant universities, including Texas A&M. We have many examples of collaborations and cooperation with our partners in the university system.

As Dr. Vitko said, right now at Plum Island, the programs now exist at Plum Island, the research programs are cooperative with Texas A&M and a number of the other university partners around the country, where the work can be done that doesn't require the on-site biosafety level 3. In some cases, those university cooperators come to the island and work in our facilities.

Mr. MCCAUL. Mr. Shea? Okay.

I yield back my time. Thank you.

Mr. LANGEVIN. I thank the gentleman.

The chair now recognizes the chairman of the full committee, Mr. Thompson, the gentleman from Mississippi, for questions.

Mr. THOMPSON. Thank you very much, Mr. Chairman.

Dr. Knipling, you mentioned the relationship between DHS and USDA as a result of the transfer of Plum Island. Can you expound a little bit on how that relationship has developed since the transfer?

Mr. KNIPLING. I would characterize it as a very fine relationship. Right from the start, we realized we had a shared responsibility. Both departments, and then within USDA, both ARS and APHIS have cooperated quite well right from the beginning. We have developed this governing structure. We have quarterly meetings and we address those issues.

So I would characterize that working relationship as quite fine.

Mr. THOMPSON. One particular aspect of that relationship was in the area of agriculture inspectors and how we were able to transfer that. Can you say to the committee whether or not the transfer has been successful? And CBP and everybody is happy now that it is one?

Mr. SHEA. Mr. Chairman, I will discuss that because that is part of the APHIS agency.

Mr. THOMPSON. Right.

Mr. SHEA. We are working very closely with CBP, and have been from the beginning. We are making great strides. There are former APHIS employees who had the leadership roles within CBP over the agriculture function. We worked very closely with them.

Yes, there are some challenges there, but most of the challenges we face in that program would have occurred regardless of any reorganization—increased international traffic, the threat of terrorism, new kinds of agricultural pests and pathways all exist. That is what we really have to deal with.

I should also add that many of the functions of the entire agricultural quarantine inspection system remained with APHIS. APHIS sets the regulations on what can come into the country and not. APHIS does the risk assessments to determine that. APHIS has many roles still in this, working closely with CBP and we think that it is, indeed, getting better every day.

Mr. THOMPSON. So those who might have reluctance about the relationship and how it has morphed into what it is today, your testimony is that you are satisfied that it is moving forward, you are being successful, and, short of any just basic things that come up, we are moving forward?

Mr. SHEA. Absolutely. We think it is moving forward. And Mr. Chairman, I know that we are all aware that some proposals have been made to return the inspection function to APHIS. Just yesterday, both Secretary Johanns and Secretary Chertoff jointly signed a letter to Senator Feinstein and others opposing such a move, because we do think that things are moving along very well, and we need to focus on continuing that improvement.

Any change in the organizational structure we think would be disruptive. It would delay the improvements that we are jointly making between USDA and CBP. We do not think it is a good idea.

Mr. THOMPSON. Can you provide the committee with a copy of this letter, jointly signed by the two secretaries?

Mr. SHEA. Absolutely, sir. We can do that.

Mr. THOMPSON. All right. Mr. Chairman, I would like at whatever point to include that letter as part of the record for this hearing.

Mr. LANGEVIN. Without objection.

Mr. THOMPSON. The last item is, have we been able to increase the number of inspectors since we have transferred that responsibility to DHS?

Mr. SHEA. Since the day of the transfer, the number of agricultural inspectors actually on board has increased by 30 percent. There were over 300 vacancies at the time of the transfer. CBP has filled all those vacancies, plus added more inspectors since then.

Mr. THOMPSON. Thank you.

I yield back, Mr. Chairman.

Mr. LANGEVIN. Just on that point, to follow up, do those inspectors also go overseas? Are there overseas facilities, or is that just here in the United States?

Mr. SHEA. The CBP inspectors are only here in the United States. APHIS still sends some inspectors overseas to pre-clear cer-

tain items, for example bulbs from Holland. So there is still some of that activity within APHIS, but not within CBP.

Mr. LANGEVIN. Was the inspection process more robust overseas prior to the transfer?

Mr. SHEA. The system is exactly the same.

Mr. LANGEVIN. Okay. Thank you.

The chair now recognizes the gentleman from North Carolina, Mr. Etheridge, for questions.

Mr. ETHERIDGE. Thank you, Mr. Chairman.

Gentlemen, thank you for being here today. Let me ask you a question, because by and large, Plum Island, as you have testified in your opening comments, has pretty much focused on foot-and-mouth disease, that has been one of the primary issues. As you well know, that is still a concern of the public, obviously, from what we have seen and what has happened.

Even though it is popularly known as mad cow disease, H5N1, the highly pathogenic Asian influenza and many other diseases could potentially devastate American agriculture as well, just as easily.

My question is, how are USDA and DHS addressing these diseases now? And number two, how would NBAF improve federal research and the response efforts to these and possibly other epidemics that we don't know about, but certainly could pop up in the future?

Mr. KNIPLING. With respect to avian influenza, there is a facility at Athens, Georgia, a biosafety level 3 facility at Athens, Georgia, that addresses avian influenza and has for more than 25 years. Fortunately, much of the information we know and the technology we have in place today was based upon the research investments made many years ago.

It is envisioned that—

Mr. ETHERIDGE. That was before the tremendous growth we have seen in recent years.

Mr. KNIPLING. That is correct. Yes.

Mr. ETHERIDGE. Thank you.

Mr. KNIPLING. At this point, in terms of the generic program of NBAF, it is not planned to do poultry research in the new facility, although the facility is being designed very generically and could adapt to any new issues or priority that comes along, including poultry. But there are separate initiatives within USDA to strengthen the avian influenza capability at Athens, Georgia in terms of facilities and expanded programs.

The mad cow disease, the transmissible spongiform encephalopathy, that work is being done at Ames, Iowa under biocontainment. We have an extensive program there on various aspects of that pathogen. These programs are, in turn, coordinated with APHIS and DHS as well.

Mr. ETHERIDGE. Since you mentioned it, let me ask one other question along that line. Currently, the secretary of agriculture has the authority to grant permits to federal agencies, state and local governments, or private persons to study live foot-and-mouth disease on the U.S. mainland, as you have indicated. To date, the secretary has not done so, and therefore FMD is only studied at Plum

Island, as you have talked about, although it is studied on the mainland in Canada.

My question is: Do you believe the secretary intends to grant such a permit to DHS for the NBAF facility? Or is congressional authority going to be required?

Mr. KNIPLING. It is our expectation that the secretary of agriculture will authorize FMD work to be done on the mainland in NBAF, and that would be for all agencies. The USDA programs now at Plum Island will be a component of the NBAF facility. So yes, the secretary of agriculture intends to do that.

Mr. ETHERIDGE. He intends to do that. Okay, thank you. That is important for this committee to know, simply because of the authorization level.

Secondly, what risks are there to studying FMD on the mainland? And how will you address this by biosecurity at NBAF? We need to know that, obviously. You touched on it earlier, but I thought I would give you an opportunity to talk about that specifically.

Mr. KNIPLING. Well, certainly the risk is that the pathogen, the live virus, would escape the facility in some manner, either through physical air movement or breaches in the physical security, or a careless worker might inadvertently carry the pathogen to the outside. But that is what biosafety level 3 protocols and structures and various rigorous adherence to that is designed to prevent.

Mr. ETHERIDGE. In the last few seconds I have, is it possible to weaponize foot-and-mouth disease? Certainly, I think a lot of us, certainly in North Carolina where I am from, with the tremendous population we have, are really concerned after what happened in Europe, whether or not it could just be intentionally spread in areas. I know that is a major concern, and whoever wants to tackle that one, it would be fine with me.

Mr. VITKO. The answer is yes. Intentional introduction of FMD is a realistic and possible concern and needs to be addressed.

Mr. ETHERIDGE. I hope you will share with us your thoughts as to how we need to address it.

Mr. VITKO. That is exactly what we are all working on, which is through the development of vaccines to give the animals immunity, but also antivirals for the period to which the immunity starts. So to mark some of the progress that has occurred at Plum, and then give you an idea of what needs to be done, one of the things we have done over the past couple of years is characterized five of the FMD vaccines that currently exist in the North American FMD vaccine bank, and ensure that they have onset of immunity within 7 days.

We have also had promising results on antivirals for bridging that timeframe. The challenge with FMD is that it is a virus that changes rapidly and exists in different, if you will, flavors. So you need to have vaccines against each of those individual serotypes or strains. It is the process of developing those that are sequential processes in the current limited space. So even doing that, we would be able to accelerate if we have NBAF.

Mr. ETHERIDGE. Thank you, sir.

Thank you, Mr. Chairman.

Mr. LANGEVIN. Thank you.

To follow up on that question, first, is it any more likely that FMD could be weaponized than, say, mad cow disease? And also, as we move into the next generation of bioweapons countermeasures, and we basically move to one drug for many bugs, would that type of technology protect us against the different mutations of FMD that you just spoke about?

Mr. VITKO. I think it is fair to say that FMD spreads much more rapidly than BSE will. Okay? That is the big thing about FMD is it is highly virulent. It is easily transmitted and will spread through your animal infrastructure.

With respect to drugs that deal with many different strains, the broad-spectrum drugs, that is exactly the kind of research that is being pursued, some by the ARS folks, some by Texas A&M and others, that are looking to take advantage of advances in genomic understanding. We have done the genome of the whole cow, to try to get that understanding and see what we can do along those ways. That is still in the research stage.

The next generation of vaccines are still targeted at individual vaccines for each of the major serotypes and strains, but again allow you to differentiate vaccinated from infected animals.

Mr. LANGEVIN. Okay, very good.

I want to thank the witnesses for their valuable testimony, and the members for their questions. The members of the subcommittee may have additional questions for the witnesses. We will ask that you respond expeditiously in writing to those questions.

Hearing no further business, the subcommittee stands adjourned.

[Whereupon, at 2:48 p.m., the subcommittee was adjourned.]

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